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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/677,328 10/02/00 GIANNESI

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EXAMINER

NIXON & VANDERHYE P. C.
8TH FLOOR
1100 NORTH GLEBE ROAD
ARLINGTON VA 22201-4714

HM12/0620

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ART UNIT	PAPER NUMBER

1625

DATE MAILED:

06/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/677,328

Applicant(s)

Giannessi, F. et al.

Examiner
Charanjit Aulakh

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1625



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-27 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1, 2, 5-9, and 11-27 is/are rejected.

7) Claim(s) 3, 4, and 10 is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)

18) Interview Summary (PTO-413) Paper No(s). 6

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1

20) Other:

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-27, drawn to compounds of formula (I) where X+ represents N+(R1, R2, R3), pharmaceutical compositions containing them and a method of using these compounds,

classified in class 564, subclass 32+.

II. Claims 1, 2 and 4-27, drawn to compounds of formula (I) where X+ represents P+ (R1, R2, R3), pharmaceutical compositions containing them and a method of using these compounds, classified in class 568, subclass 8.

2. The inventions I and II as defined above are patentably distinct, each from the other since they are structurally so divergent that a reference showing compounds of invention I would not render compounds of invention II *prima facia* obvious. Search required for compounds of invention I in class 564 is not the same search required for compounds of invention II in class 568 and therefore, constitutes as burdensome search. Thus, restriction requirement as indicated above is proper.

3. During a telephone conversation with the applicant's attorney, Mr. Arthur R. Crawford on March 22, 2001, a provisional election was made with traverse to prosecute the invention of group I (example 15 on page 56 as species), claims 1-27. Affirmation of this election must be

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made by applicant in replying to this Office action. Claims 1, 2 and 4-27 are generic and therefore, have been examined to the extent that they read upon the elected group I.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

5. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Italy on May 15, 1998. It is noted, however, that applicant has not filed a certified copy of the MI98A00175 application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 12, 15, 16, 19, 22, 26 and 27 provides for the use of compounds as medicaments or pharmaceutical compositions for treatment of diabetes, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to

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encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

8. Claims 16 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 16, the term "glycaemia" is indefinite since its meaning is not clear. Should it be glycemia?

In claim 23, the term "triglyceridhemia" is indefinite since its meaning is not clear. Should it be triglyceridemia?

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 12, 15, 16, 19, 22, 26 and 27 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

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Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claims 1, 2, 5-9 and 11-27 are rejected under 35 U.S.C. 102(a) as being anticipated by

Shinagawa (J. Med. Chem., cited on applicants form 1449).

Shinagawa discloses Emeriamine and its analogues, a process for preparing them and their utility as hypoglycemic and antiketogenic agents (page 1458, first paragraph). The compounds no. 13 and 14 (see table II) and a process for preparing compounds 13-16 and 18 (see scheme II) of Shinagawa anticipates the instant claims when Z represents NHCOOR4, NHCOR4 and NHR4 groups in the instant compounds of formula (I).

IMPROPER MARKUSH GROUP

12. Claims 1,2 and 4-27 are objected as being directed to Improper Markush Group since variable X+ is critical for the common core of the instant compounds. The applicants are suggested to amend the claims to read upon the elected group to overcome this objection.

Allowable Subject Matter

13. Claim s 3, 4 and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chana Aulakh whose telephone number is (703) 305-4482. The examiner can normally be reached on "Monday-Thursday" from 7:30 A.M. to 6:00 P.M. If the attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Jyothsna Venkat, can be reached on (703) 308-2439. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group's receptionist whose telephone number is (703) 308-1235.

C. S. Aulakh
CHARANJIT S. AULAKH

PRIMARY EXAMINER